K050169
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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name: **Health & Life Co., Ltd.**

Address: 9 F, No. 168, Jian Yi Road, Chung Ho City, Taipei County , Taiwan
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Phone: 886-2-82271300

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Contact: Mr. Paul Yang / President

2.0 Device Name **HL 200 ELECTRONIC STETHOSCOPE**

Trade Name Model No. : **HL 200**

Common Name: **Electronic Stethoscope**

Classification name: **Stethoscope, Electronic**

3.0 Classification: Class II

4.0 Predicate Device:

- **3M Littmann Model 2000 Electronic Stethoscope (K961848)** marketed by **3M Health care**.

5.0 Device Description: **HL 200 ELECTRONIC STETHOSCOPE** is a non-sterile, reusable Electronic Stethoscope . **HL 200 ELECTRONIC STETHOSCOPE,** equipped with built-in micro-computer chip, includes state-of-the-art amplification and filtering systems. It is ideal for picking up difficult-to-hear heart and other body sounds. The features of **HL 200 ELECTRONIC STETHOSCOPE** is as follows

- Providing three-mode choices for adequate requirements: heart sound mode, lung sound mode and combination mode
- Eight volumes levels provide up to 18X amplification of acoustic stethoscopes
- Electronic design with fully eliminates sound loss and resonance effects associated with traditional acoustic stethoscopes. With amplified signal, you could even hear the slight sounds much clearer than the traditional one.
- Ergonomically designed with comfortable handholding, subtle with material and touch
- Four-segments display shows the battery conditions could inform you to know the battery using state
- Auto shut-off after 3 minutes for extending battery life

6.0 Intended Use: The **HL 200 ELECTRONIC STETHOSCOPE** is intended for medical diagnostic purposes only. It can be used for the amplification heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

7.0 Performance Summary: In terms of performance specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 and IEC 60601-1-2 & related requirements.

8. Conclusions:

The **HL 200 ELECTRONIC STETHOSCOPE** have the same intended use and similar technological characteristics as the **3M Littmann Model 2000 Electronic Stethoscope (K961848)** marketed by **3M Health care**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **HL 200 ELECTRONIC STETHOSCOPE** is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2005

Health & Life Co., Ltd.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
3892 South America West Trail
Flagstaff, AZ 86001

Re: K050169
Trade Name: HL 200 Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: II (two)
Product Code: DQD
Dated: March 17, 2005
Received: March 24, 2005

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050169

Indications for Use

510(k) Number (if known):_____

Device Name: **HL 200 ELECTRONIC STETHOSCOPE**
Health & Life Co., Ltd.

Indications For Use:

The **HL 200 ELECTRONIC STETHOSCOPE** is intended for medical diagnostic purposes only. It can be used for the amplification heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Chamman
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050169